K 043599

product for over the counter use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the products and their appropriateness for commercial distribution.

FEB 2 5 2005

510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: Moments Menopause Check Model 9113

Description: Immunoassay for the qualitative detection of FSH in urine.

Name Of Manufacturer: Phamatech
10151 Barnes Canyon Road
San Diego, California 92121, USA

Intended Use: The Moments Menopause Check is a rapid, qualitative immunoassay for the detection of follicle stimulating hormone (FSH) in urine. The minimum detectable concentration for this test is 25 mIU/ml. This assay is intended for use in the home to assist in the early detection of menopause.

Technology: The Moments Menopause Check, like many commercially available FSH screening tests, qualitatively measures the presence of follicle stimulating hormone by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Phamatech (San Diego, CA) Moments Menopause Check (Models 9111 and 9112) and the Estroven Menopause Monitor (Distributed by Amerifit Nutrition, Inc. Bloomfield, CT). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / FSH / colored (labeled) antibody complexes.

Performance: The product performance characteristics of the Moments Menopause Check were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Moments Menopause Check to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of follicle stimulating hormone in urine. Laboratory studies, using clinical specimens, produced a >98% correlation when compared to the predicate devices.

A consumer study was also performed, in it the Moments Menopause Check exhibited excellent overall accuracy. Consumer interpretation of the FSH test showed accuracy to be greater than 98%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 25 2005

Mr. Carl Mongiovi
Vice President
Phamatech, Inc.
10151 Barnes Canyon Road
San Diego, CA 92121

Re: k043599
Trade/Device Name: Moments Menopause Check (Model 9113)
Regulation Number: 21 CFR 862.1300
Regulation Name: Follicle-stimulating hormone test system
Regulatory Class: Class I
Product Code: CGJ
Dated: February 14, 2005
Received: February 17, 2005

Dear Mr. Mongiovi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K043599

Device Name: Moments Menopause Check (Model 9113)

Indications for Use:

The Moments Menopause Check is an in-vitro diagnostic screen for the detection of FSH (follicle stimulating hormone) in urine. Change in FSH levels may be associated with stages in menopause. This kit provides a preliminary result for the detection/presence of FSH in urine. It is intended for over-the-counter sales.

Prescription Use:_____ AND/OR Over the Counter__X__

Part 21 CFR 801 Subpart D 21 CFR 807 Subpart C

Concurrence of CDRH Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510 (k): K043599